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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,936

10/20/2005

David Jackson

23133-09967

1891

758 7590 12/30/2009

FENWICK & WEST LLP  
SILICON VALLEY CENTER  
801 CALIFORNIA STREET  
MOUNTAIN VIEW, CA 94041

EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

12/30/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,936	<b>Applicant(s)</b> JACKSON ET AL.	
	<b>Examiner</b> DAVID LUKTON	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-100 is/are pending in the application.
- 4a) Of the above claim(s) 4, 10, 12-14, 26-30 and 40-100 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34-39 is/are allowed.
- 6) ☒ Claim(s) 1, 5-8, 11, 18, 19, 21 and 23 is/are rejected.
- 7) ☒ Claim(s) 9, 15-17, 20, 22, 24, 25 and 31-39 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

Pursuant to the response filed 9/25/09, claims 2-4 have been cancelled, and claims 1 and 34 amended. Claims 1 and 5-100 are now pending.

Claims 1, 5-9, 11, 15-25, 31-39 are examined in this Office action; claims 4, 10, 12, 13, 14, 26-30, 40-100 are withdrawn.

Claims 34-39 are now characterized as allowable. Claims 1, 5-8, 11, 18, 19, 21, 23 are rejected in this Office action. Claims 9, 15-17, 20, 22, 24, 25, 31-39 are objected to because of their dependence on rejected claims.

▲

The following is a quotation of 35 USC, §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1, 5-8, 11, 18, 19, 21, 23 are rejected under 35 U.S.C. §103 as being unpatentable over Nardin (*Vaccine* **16**, 590-600, 1998).

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The teachings of the reference were indicated previously.

In response, applicants have argued the following:

“Nardin does not disclose constructs wherein one of the two required epitopes (i.e., the Th or CTL epitope) is located on the C-terminal side of an internal lysine residue to which a lipid moiety is also attached, and the other different epitope (i.e., the epitope type not present on the C-terminal side) is located on the N-terminal side of the lysine residue, as required by the amended claims”

However, applicants assertion about what claim 1 requires is not accurate. By way of contrast, suppose that the following phrase were added to the end of claim 1:

with the proviso that either one of conditions (a) and (b) is met, wherein condition (a) and condition (b) are defined as follows:

condition a: the Th epitope is located on the C-terminal side of the internal lysine residue that bears the lipid residue **and** the CTL epitope is located on the N-terminal side of the lysine residue **and** the C-terminal side of the internal lysine residue that bears the lipid residue does not also contain a CTL epitope **and** the N-terminal side of the lysine residue that bears the lipid residue does not also contain a Th epitope;

condition b: the CTL epitope is located on the C-terminal side of the internal lysine residue that bears the lipid residue **and** the Th epitope is located on the N-terminal side of the lysine residue **and** the C-terminal side of the internal lysine residue that bears the lipid residue does not also contain a Th epitope **and** the N-terminal side of the lysine residue that bears the lipid residue does not also contain a CTL epitope.

That is, there is nothing in claim 1 that precludes the possibility that the N-terminal side of the lysine (bearing the lipid group) contains both the CTL epitope and the Th epitope, and that the same is true of the C-terminal side of the lysine (that bears the lipid group).

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Since this embodiment is not excluded, it is included, and the rejection is directed at this embodiment.

Applicants have also argued the following:

“Nardin discloses branched constructs in which a lysine residue attached to the epitopes is positioned at the N-terminal end of the construct in a ‘template core’. Figure 1E of Nardin (when read in conjunction with Figures 1B and 1C) shows that a lysine residue is located at the C-terminus of the ‘template core’ comprising the two epitopes”.

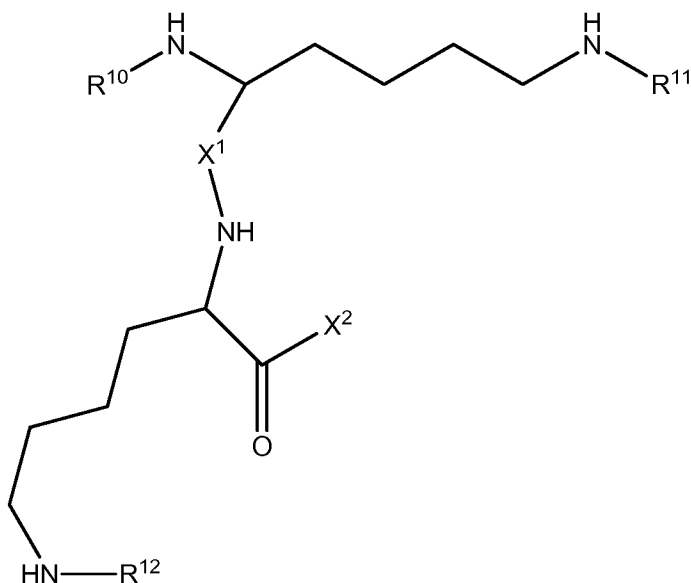
Notably absent from claim 1 is any mention of a “C-terminus” or an “N-terminus”.

Also absent from claim 1 is any mention of a “template core”. Also absent from claim

1 is any suggestion or innuendo that branched peptides might be excluded. Consider

the structures in figure 1 of the reference, particularly those of figure 1E. These can be

represented as follows:



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Here,  $R^{10}$  and  $R^{11}$  are groups that contain the requisite epitopes,  $X^1$  is a peptide linking moiety,  $X^2$  is a peptide group, and  $R^{12}$  is Pam<sub>3</sub>Cys. As it happens, this structure meets the requirement recited in the last three lines of claim 1, i.e.: “an internal lysine ... to which a lipid moiety is attached is positioned between the Th epitope and the CTL epitope”.

Applicants have also argued that they have demonstrated “unexpected results”, i.e., that compounds containing a lipid group at an internal position provide a greater T cell response than those containing a lipid group at the N-terminal position. However, the examiner has not argued that Nardin discloses linear peptides bearing a lipid group at the N-terminal position, nor has he argued that it would have been obvious to take such a peptide (which is not disclosed in Nardin) and to move the lipid to an internal position. Whatever the merits of applicants’ data, it is not effective to overcome this ground of rejection.

The rejection is maintained.

▲

Claims 1, 5-8, 11, 18, 19, 21, 23 are rejected under 35 U.S.C. §103 as being unpatentable over Tam (USP 5,580,563).

As indicated previously, Tam discloses (figure 1) a vaccine in which antigens are present, and a lipophilic group is bonded to an internal lysine. Also disclosed (e.g., col 5, line 55+) is that Th and CTL epitopes can both be present.

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In response, applicants have merely asserted that the reference does not disclose a lipopeptide in which an internal lysine .... to which a lipid moiety is attached is positioned between the Th epitope and the CTL epitope. Applicants have not elaborated further, but one might assume that they intend for the arguments presented in the traversal over the Nardin rejection to apply as well. And the examiner does the same.

And to add to the foregoing, much depends on precisely what is meant by the word “between” in line 13 of claim 1. For example, one can say, with justification, that the state of North Dakota lies “between” Virginia and California, despite the fact that a line drawn between the northernmost tip of VA and the northern tip of CA does not intersect ND. In addition, one can interpret the term “lipid moiety” somewhat liberally, as it is clear that this term can include a lipid to which is attached one amino acid, and maybe more.

Thus, in the Tam compounds, the “lipid moiety” does lie “between” the two epitopes in question, even if one makes the erroneous assumption that organic structures are “flat” and that there is no freedom of motion.

^

Claims 1, 5-8, 11, 18, 19, 21, 23 are rejected under 35 U.S.C. §103 as being unpatentable over Tam (USP 5,580,563) in view of Sauzet (*Vaccine* **13**(14), 1263-1384, 1995).

The rejection is maintained for the reasons above.

^

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/

Primary Examiner, Art Unit 1654